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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/438,030 | 11/10/1999 | Mir A Imran | PERCUS.093A | 8801 |

20995 7590 11/19/2002

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IRVINE, CA 92614

[REDACTED] EXAMINER

SERKE, CATHERINE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3763 | 14 |

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/438,030 | IMRAN ET AL. |
| | Examiner Catherine Serke | Art Unit 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 September 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3-39 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 3-20, 31-39 and 47 is/are allowed.
- 6) Claim(s) 21, 23-28, 30, 48-51 and 54-57 is/are rejected.
- 7) Claim(s) 22, 29, 52 and 53 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auth et al ('229).

Auth discloses a device and method steps for a percutaneous aspiration thrombectomy catheter system that includes delivering a guidewire so that its distal end is distal to an occlusion; delivering an aspiration catheter until its distal end is proximal to the occlusion; and crossing the site of the occlusion with the distal end of the aspiration catheter while aspirating. The specification teaches that “The use of the pump makes it easy to advance the catheter tip through the thrombus with a steady vacuum level.” (see 4:47-49) [Emphasis added] Since the catheter tip is advancing through (crossing) the thrombus and the catheter tip is angled back from the guidewire (see figures), the guidewire tip itself must be delivered distal to the occlusion before the aspiration step. After the aspirating step the aspiration catheter may be removed and another catheter can be advanced over the guidewire. (6:1-6)

Auth meets the claim limitations of removing the aspiration catheter and advancing another catheter but fails to specifically teach advancing a therapy catheter.

At the time of the invention, it would have been obvious to advance a rapid exchange balloon angioplasty catheter over the guidewire. The motivation for this can be found in the

specification (5:25-27) which teaches dilating the lesion after aspirating. Since the most of the embodiments do not teach having a dilation balloon integral with the aspiration catheter it would be obvious in light of the teaching to advance a dilation balloon catheter over the guidewire after removal of the aspiration catheter.

Claims 21, 23-28, 30, 48-49 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auth et al ('229) in view of Imran ('650).

Auth meets the claim limitations as described above but fails to include the use of a guidewire with an occlusive device or exchanging the guidewire for a guidewire with an occlusive device.

Imran discloses an analogous invention for removing occlusions using aspiration methods and includes the use of a guidewire with a distal occlusion member.

At the time of the invention, it would have been obvious to incorporate a guidewire with an occlusive device at the distal end of the guidewire as taught by Imran into the invention of Auth in order to further prevent debris from traveling in a distal direction from the aspiration catheter. The motivation for capturing debris by the occlusion device is found in Imran (1:26-29).

Allowable Subject Matter

Claims 3-13, 14-20, 31-33, 34-39 and 47 are allowed.

Claims 22, 29 and 52-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

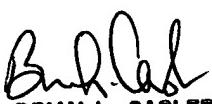
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke 
November 6, 2002



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700